Louisiana Medicaid
Infectious Disorders – Antibiotics – Gastrointestinal (GI) Antibiotics

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred GI antibiotics.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details*

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.;
  AND
- For Xifaxan® (rifaximin):
  - When used in the treatment of **moderate-to-severe travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli***:
    - The recipient is 12 years of age or older on the date of the request; **AND**
    - The recipient's diagnosis is noninvasive TD caused by *Escherichia coli*; **AND**
    - The maximum dose is 200mg 3 times a day for 3 days; **AND**
    - For moderate TD (diarrhea that is distressing or interferes with planned activities):
      - The recipient has had a *treatment failure, intolerable side effect* or *documented contraindication(s)* to azithromycin; **AND**
      - The recipient has had a *treatment failure, intolerable side effect* or *documented contraindication(s)* to fluoroquinolones; **OR**
    - For severe nondysenteric TD (diarrhea that is incapacitating or completely prevents planned activities):
      - The recipient has had a *treatment failure, intolerable side effect* or *documented contraindication(s)* to azithromycin, which is preferred to treat severe TD; **AND**
      - The recipient has had a *treatment failure, intolerable side effect* or *documented contraindication(s)* to fluoroquinolones, which may be used to treat severe, nondysenteric TD; **OR**
  - When used in the treatment of **irritable bowel syndrome with diarrhea (IBS-D)**:
    - The recipient is 18 years of age or older on the date of the request; **AND**
    - The maximum dose is 550mg 3 times a day for 14 days followed by a 10-week treatment-free period; **AND**
    - If a *second* treatment is needed for recurrence of IBS-D signs and symptoms after the 10-week treatment-free period, the maximum dose is 550mg 3 times a day for 14 days followed by a 10-week treatment-free period; **AND**
    - If a *third and final* treatment is needed for recurrence of IBS-D signs and symptoms after the 10-week treatment-free period, the maximum dose is 550mg 3 times a day for 14 days.

    - When used to reduce the risk of **hepatic encephalopathy** recurrence:
        - The recipient is 18 years of age or older; **AND**
        - The maximum dose is 550mg 2 times a day
- For all other GI antibiotics, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber states that the request is to *complete a course of treatment that was initiated while the recipient was in an inpatient facility*; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested GI antibiotic (e.g., fever, dysentery or blood in the stool if the request is for rifaximin) and will not be receiving the requested GI antibiotic in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval for rifaximin for travelers' diarrhea

- Rifaximin used for travelers' diarrhea – 3 days

Duration of initial and reauthorization approval for other GI antibiotics and other uses of rifaximin

- Rifaximin used for irritable bowel syndrome with diarrhea – 14 days
- Rifaximin if needed for a *second course* **OR** a *third and final course* of treatment for irritable bowel syndrome with diarrhea – 14 days (with a 10-week treatment free period between treatment courses)
- Rifaximin used for hepatic encephalopathy – 12 months
- GI antibiotics for indications other than hepatic encephalopathy – 1 week to 3 months determined based upon patient-specific factors and the condition being treated

References

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Prevention, Centers. "Travelers' Diarrhea - Chapter 2 - 2018 Yellow Book | Travelers' Health | CDC". wwwnc.cdc.gov, 2019, https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/travelers-diarrhea

Xifaxan (rifaximin) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; October 2020. https://shared.salix.com/shared/pi/xifaxan550-pi.pdf

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
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